

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-12 are pending in the present application. Claims 1-4 have been amended to address formal matters recently detected in the claims. Claims 5-11 have been rewritten as method claims. As the Examiner is aware, claims 5-11 were previously directed to "use" claims, which are not permitted under United States patent practice and often pursued as method claims. As claims 5-11 now recite method claims that utilize the claimed product, applicants request that claims 5-11 be rejoined with product claims 1-4 and 12. New claim 12 has been added. Support for new claim 12 may be found in original claim 1.

In the outstanding Official Action, claims 2-4 were rejected under 35 USC §112, first paragraph, as allegedly not satisfying the written description requirement. This rejection is respectfully traversed.

Applicants believe that the outstanding Official Action fails to satisfy its burden in showing that the present disclosure does not satisfy the written description requirement. As the Examiner is aware, an applicant's disclosure need only reasonably convey to the skilled artisan that as of the filing date of the application relied upon, the applicant had possession of the specific subject matter claimed. *Vas-Cath, Inc. v.*

Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). Claim 2 is directed to an isolated peptide having sequence-identity of at least 60% with SEQ ID NO: 1, and wherein said peptide is an inhibitor of platelet derived growth factor and fibroblast growth factor. Claim 3 recites an isolated peptide having electric-charge homology or hydrophilicity or hydrophobicity or solvent-exposure rate or three-dimensional confirmation of at least 60% with SEQ ID NO: 1. Claim 4 recites a peptidic or non-peptidic molecule showing conformational similarity or functional-group disposition similarity, of at least 60% with SEQ ID NO: 1.

Upon reviewing claims 2-4, it is apparent that claims 2-4 are identified by their structure, properties and/or function. As a result, applicants believe that one of ordinary skill in the art would recognize that applicants were in possession of the claimed invention at the time the application was filed. Indeed, the Official Action fails to cite to any evidence to the contrary.

As a result, applicants believe that the outstanding Official Action fails to satisfy its burden in showing that the present disclosure does not satisfy the written description requirement.

In the outstanding Official Action, claims 1-4 were rejected under 35 USC §102(b) as allegedly being anticipated by BAIRD et al. This rejection is respectfully traversed.

Applicants believe that BAIRD et al. fail to anticipate the claimed invention. As the Examiner is aware, to constitute anticipation, all material recitations of a claim must be found in one prior art source, which must be enabling to one skilled in the art, i.e., enable that person to understand the nature and operation of the invention. *Seymore v. Osborne*, 78 USPQ 516 (USSC 1870); *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). Upon reviewing the BAIRD et al. publication, applicants believe that the BAIRD et al. publication fails to qualify as an enabling publication.

BAIRD et al. teach peptides of 45 residues or greater along with the synthesis of peptides of 30 residues or greater (column 4, lines 20-58). BAIRD et al. state that a peptide of length functions as an antagonist and that this function is achieved only with a peptide of this length. In other words, BAIRD et al. teach away from the selection of a smaller peptide as recited in the claims.

In addition, applicants note that the present peptide has its own evolutive history, as demonstrated by the presence of three different exons within the FGF-2 sequence (ABRAHAM et al. EMBO 1986, 5(10):2523-8) (Genbank accession numbers X04431, X04432, X04433, respectively). This means that the "evolutive history" of the sequence is of a different process from the evolutive history of each of its exons, indicating a different

evolutive pressure on different portions of the gene. Therefore, each of the portion sequence is not the same.

The present peptide also has its own structural conformation, which is not an equivalent to any of the portions reported in the examples of BAIRD et al., and is different from the structural conformation of the entire FGF-2 sequence itself. See X-ray based FGF-2 structure reported by Plotnikov Cell 1999, 98, 641-650, Plotnikov Cell, 2000, 101413-424; Facchiano JBC 2003, 10, 8751-8760. None of the examples reported by BAIRD et al. report a sequence matching both the sequence and the length of the claimed sequence. Therefore, the claimed specific region cannot be considered structurally equivalent to a shorter or longer region disclosed by BAIRD et al.

In addition, as noted above, the claimed peptide has its own functional feature. Moreover, no other portion of a sequence indicated by the BAIRD et al. examples has the same specific activity to inhibit FGF-2 dimerization, inhibit FGF-2 heparin binding, inhibit cell proliferation and chemotaxis induced by FGF-2 (see FACCHIANO et al. J. Biol Chem. 2003; 278(10):8751-60). Therefore, the claimed specific region cannot be considered functionally equivalent to the entire sequence or to any of the portions indicated by BAIRD et al.

Moreover, the claimed sequence has its own "molecular stability" and half-life, which differs from the molecular stability of the entire sequence or any of its portion indicated

in the examples by BAIRD et al. In fact, according to the "N-end rule" (see Varshavsky A cell 1992, 69(5), 725-735; Madura K, Science 1994, 265 (5177) 1454-1458), a proteins half-life strictly depends on the sequence and N-terminal residues. Therefore, the claimed sequence has a specific half-life and molecular stability distinct from that of entire FGF-2 sequence or any portion reported by BAIRD et al.

Thus, in view of the above, applicants believe that BAIRD et al. fails to qualify as an enabling reference. As BAIRD et al. fails to qualify as an enabling reference, applicants believe that BAIRD et al. fails to anticipate the claimed invention.

In view of the present amendment and foregoing remarks, therefore, applicants believe that the present application is in condition for allowance, with claims 1-12, as presented. Allowance and passage to issue on that basis is respectfully requested.

Please charge the fee of \$200 for the extra independent claim added herewith, to Deposit Account No. 25-0120.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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